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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,816	09/30/2003	Johann J. Neisz	AMS-029B	6669
22850	7590	03/10/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			GILBERT, SAMUEL G	
			ART UNIT	PAPER NUMBER
			3735	
DATE MAILED: 03/10/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/675,816	NEISZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Samuel G. Gilbert	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,6-14,36-39,42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-8,12-14,36-39,42 and 43 is/are rejected.
- 7) ☒ Claim(s) 2 and 9-11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/14/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/7/2005 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 13, and 37-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Kammerer et al (2002/0077526). The applicant's attention is invited to Figure 3a and Figure 4. The examiner is taking element –112- as a dilator and the method is set forth in figure 4 and the related written description. The examiner is taking the position that the applicant does not have support for the embodiment as

Art Unit: 3735

claimed in claims 37-39 prior to the filing date 7/27/2001 of US patent application 10/005,837. The filing date for Kammerer et al is 6/4/2001.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 7, 8, 36 and 43 rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman 2002/0058959.

Claims 1, 36, and 43 – element –450- is a sling, element –420- is a first needle, and element –440- is a dilator for association of the first needle with the sling.

Gellman teaches that the needle used for the procedure can be any of a variety of needles, paragraph [0036] lines ¾ and paragraph [0037] set forth a variety of needles that may be used. The method as set forth only uses one needle. As set forth the kit of claim 1 does not require any particular association of the two needles only that two different types of needles are present in the kit. It is the examiner's position that before starting the procedure a variety of needles as set forth in Gellman are all available to the surgeon and are considered a kit. The surgeon would select among these types of needles based on the particular patient and personal preference of the surgeon to

select the particular first needle connected to the dilator as set forth in Gellman. The examiner is taking this group of possible needles to be part of the claimed kit.

Claim 3 – pouch -470- is a sheath.

Claim 4 – the dilator associates the sling and the needle.

Claims 7 and 8 – the needle can include an hole, eyelet –24-, paragraph [0036]

Claims 6, 12 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman as applied to claim 1 above and further in view of Landgrebe 2002/0091298.

Gellman teaches system as claimed but does not set forth a plurality of handles for the needles. Landgrebe teaches a plurality of different handles for use with surgical needles. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a plurality of handles available for each of the needles in the kit to allow the surgeon to select the desired handle based on patient conditions and personal preference. A plurality of handles provides the benefit of selecting the handle that best fits the surgeon's hand/hands.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kammerer et al 2002/0077526 in view of Allosling Fascia, 1999. Kammerer et al teaches a device as claimed but does not teach the use of a bladder perforation detector. Allosling teaches a suture passer for incontinence surgery including a leak detection sheath for detecting bladder perforation. It would have been obvious to one of

ordinary skill in the art at the time the invention was made to include the detection means as taught by Allosling with the sling system of Kammerer et al to provide the advantage of having the sling delivery system to allow the user to determine if the bladder has been perforated without withdrawing the sling delivery system and inserting a separate detection device.

### ***Double Patenting***

Claims 38 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/280,945. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 anticipates claims 38 and 39. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **37 CFR 1.105 REQUIREMENT FOR INFORMATION**

Applicant (or the assignee of this application if the assignee has undertaken the prosecution of the application) is required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

There are numerous other co-pending applications and issued patents, which disclose and claim very similar and/or identical subject matter. In accordance with 37 CFR 1.105 and MPEP 704.11(a) subsection G, applicant (or the assignee) is respectfully requested to disclose all co-pending applications and related patents (please see the non-exhaustive list below of applications and issued patents that the USPTO believes may be related) and identify the specific claims of those applications and/or patents which may present double patenting issues with the instant application claims. This requirement is reasonably necessary to examination because, based on an initial review of the applications, there is a significant degree of overlap in claimed subject matter, thus requiring an analysis of commonality of claimed subject matter to determine patentability under 35 USC 101 double patenting and/or obviousness type double patenting. Because the applicant (or the assignee) is presumably far more cognizant of the contents of the claims in these applications than any Office staff, and has access to the source documents by which such comparison could be done better than within the Office, it is reasonable to require the applicant to provide the information needed to determine the commonality among the claims.

Should applicant (or the assignee) believe that Double Patenting exists, then applicant (or the assignee) is invited to file Terminal Disclaimers and/or amend the currently pending claims in the interest of expediting the prosecution of the current application. Applicant (or the assignee) should note that a terminal disclaimer is effective to

Art Unit: 3735

overcome an obviousness type double patenting rejection, but will not overcome a

“same type” double patenting rejection under 35 U.S.C. § 101.

Non-exhaustive list of possible related co-pending applications and patents:

6612977  
6802807  
6652450  
6702827  
6641525  
6648921  
6802846  
6971986

10/133,271  
10/155,710  
10/193,716  
10/233,349  
10/274,524  
10/306,179  
10/377,101  
10/386,897  
10/616,925  
10/616,926  
10/616,938  
10/646,082  
10/675,816  
10/793,903  
11/064,875  
11/166,277  
11/202,315  
11/203,136  
11/245,364



***Allowable Subject Matter***

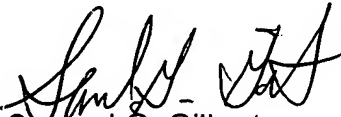
Claims 2 and 9-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571-272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Samuel G. Gilbert  
Primary Examiner  
Art Unit 3735